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(54) PROTON PUMP-INHIBITOR-CONTAINING CAPSULES WHICH COMPRISE SUBUNITS DIFFERENTLY STRUCTURED FOR A DELAYED RELEASE OF THE ACTIVE INGREDIENT

(71) Applicants: Isa Odidi, Toronto (CA); Amina Odidi, Toronto (CA)

- (72) Inventors: **Isa Odidi**, Toronto (CA); **Amina Odidi**, Toronto (CA)
- (73) Assignee: INTELLIPHARMACEUTICS CORP., Toronto, Ontario (CA)
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(58) Field of Classification Search

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(56) References Cited

U.S. PATENT DOCUMENTS

2,540,979 A	2/1951	Macdonnell	
3,254,088 A	5/1966	Juda et al.	
3,493,657 A	2/1970	Lewenstein	
3,629,393 A	12/1971	Nakamoto et al.	
3,728,445 A	4/1973	Bardani	
3,773,955 A	11/1973	Pachter	
3,789,117 A	1/1974	Tsujino	
3,819,706 A	6/1974	Mehta	
3,845,770 A	11/1974	Higuchi	
3,856,721 A	12/1974	Fritschell	
3,916,899 A	11/1975	Theeuwes et al.	
4,008,719 A	2/1977	Theeuwes	
4,016,880 A	4/1977	Theeuwes	
4,034,758 A	7/1977	Theeuwes	
4,036,228 A	7/1977	Theeuwes	
	(Continued)		

FOREIGN PATENT DOCUMENTS

CA	2286684 A1	10/1998	
CA	2539984 A1	12/2004	
	(Continued)		

OTHER PUBLICATIONS

Supplemental European Search Report Prepared by Miralles J. Gimerez Aug. 23, 2012 Supplemental European Search Report Prepared by Antonio Raposo Aug. 2, 2012.

Torpac, Capsul Size Chart, 2000, pp. 1-3.

Anderson, M. et al., Analysis of Film Coating Thickness and Surface Area of Pharmaceutical Pellets using Fluorescence Microscopy and Image Analysis, J. Pharmaceutical and Biomedical Analysis, (2000), vol. 22, pp. 325-339.

Arora, S. et al, Pulsatie Drug Delivery Systems: An Approach for Controlled Drug Delivery, Indian J. Pham. Sc., (2006), vol. 68, pp. 295-300.

(Continued)

Primary Examiner — Kyle Purdy (74) Attorney, Agent, or Firm — Thomas Horstemeyer, LLP

(57) ABSTRACT

An oral pharmaceutical composition comprises multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising: a first population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a first rate; a population of a basic substance; and a second population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a second rate. In another embodiment, the oral pharmaceutical composition comprises multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising: a population of a pharmaceutical active; a population of a basic substance; a population of enteric coated pharmaceutical active; and a population of enteric coated basic substance. The composition can provide multiple site specific delivery of a pharmaceutical active in a rapid, delayed and/or sustained release manner into the plasma.

41 Claims, No Drawings